

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
NORFOLK DIVISION**

PFIZER INC., PFIZER LIMITED, and  
PFIZER IRELAND PHARMACEUTICALS,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.

Defendants.

Civil Action No. 2:10-cv-00128-RBS-FBS

**PLAINTIFFS' ANSWER TO COUNTERCLAIMS  
OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.**

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively "Pfizer"),  
by and through their undersigned attorneys, hereby reply to the counterclaims of Teva  
Pharmaceuticals USA, Inc. ("Teva").

1. In response to paragraph 1 of Teva's Counterclaims, Pfizer reaffirms and  
realleges the allegations set forth in paragraphs 1-41 of Pfizer's Complaint (D.I. 1).

2. Pfizer denies the allegations contained in paragraph 2 of Teva's Counterclaims,  
except admits that Teva asserts that its counterclaim is an action for a judgment declaring both  
that the claims of the '012 patent are invalid and unenforceable and that Teva has not infringed  
and will not infringe any claim of the '012 patent either directly or indirectly. Pfizer also admits  
that the '012 patent is attached to Pfizer's complaint.

3. Upon information and belief, Pfizer admits the allegations contained in paragraph  
3 of Teva's Counterclaims.

4. Pfizer admits the allegations contained in paragraph 4 of Teva's Counterclaims.

5. Pfizer admits the allegations contained in paragraph 5 of Teva's Counterclaims.

6. Pfizer admits the allegations contained in paragraph 6 of Teva's Counterclaims.

7. Paragraph 7 of Teva's Counterclaims sets forth legal conclusions to which no response is required.

8. Paragraph 8 of Teva's Counterclaims sets forth legal conclusions to which no response is required.

9. Paragraph 9 of Teva's Counterclaims sets forth legal conclusions to which no response is required. Pfizer does not dispute that it is subject to personal jurisdiction in this Judicial District.

10. Paragraph 10 of Teva's Counterclaims sets forth legal conclusions to which no response is required.

11. Pfizer denies the allegations contained in paragraph 11 of Teva's Counterclaims, except admits that an actual case or controversy exists between Teva and Pfizer regarding the validity and infringement of claims 25 and 26 of the '012 patent. To the extent that paragraph 11 of Teva's Counterclaims sets forth legal conclusions, no response is required.

12. Pfizer admits the allegations contained in paragraph 12 of Teva's Counterclaims.

13. Pfizer denies the allegations contained in paragraph 13 of Teva's Counterclaims.

14. Pfizer denies the allegations contained in paragraph 14 of Teva's Counterclaims.

15. Pfizer denies the allegations contained in paragraph 15 of Teva's Counterclaims.

16. Pfizer admits the allegations contained in the first sentence of paragraph 16 of Teva's Counterclaims. Pfizer denies the allegations contained in the second and third sentences of paragraph 16 of Teva's counterclaims. To the extent that paragraph 16 of Teva's Counterclaims sets forth legal conclusions, no response is required.

17. Pfizer denies the allegations contained in paragraph 17 of Teva's Counterclaims and refers to the Canadian '446 patent and to that patent as originally issued with respect to their contents.

18. Pfizer denies the allegations contained in paragraph 18 of Teva's Counterclaims, except admits that on June 5, 2002, Bayer AG and Bayer Inc. filed a Statement of Claim against Pfizer in Canadian Federal Court with respect to the Canadian '446 patent and refers to the Statement of Claim with respect to its contents.

19. Pfizer denies the allegations contained in paragraph 19 of Teva's Counterclaims, except admits that Pfizer disclaimed certain subject matter in the claims of the Canadian '446 patent and refers to the disclaimers with respect to their contents.

20. Pfizer denies the allegations contained in paragraph 20 of Teva's Counterclaims, except admits that the Canadian Disclaimer was signed by Susan Webb, director, for Pfizer R&D, and refers to the Canadian Disclaimer with respect to its contents.

21. Pfizer denies the allegations contained in paragraph 21 of Teva's Counterclaims and refers to the Canadian Disclaimer with respect to its contents.

22. Pfizer denies the allegations contained in paragraph 22 of Teva's Counterclaims, except admits that Andrew McIntosh of Bereskin & Parr, Pfizer R&D's outside counsel, filed the Canadian Disclaimer with the CIPO on November 14, 2002. Upon information and belief, Pfizer further admits that attorneys at Bereskin & Parr spoke with Peter Ellis prior to the filing of the Canadian Disclaimer with the CIPO.

23. Pfizer denies the allegations contained in paragraph 23 of Teva's Counterclaims, except admits that Pfizer filed a second disclaimer with respect to the Canadian '446 patent on

April 29, 2004, and refers to the disclaimers filed with respect to the Canadian '446 patent with respect to their contents.

24. Pfizer denies the allegations contained in paragraph 24 of Teva's Counterclaims, except admits that Dr. Ellis executed an affidavit (the "Ellis Affidavit") on October 4, 2005, in connection with a Canadian Federal Court lawsuit involving the Canadian '446 patent in and refers thereto with respect to its contents.

25. Pfizer denies the allegations contained in paragraph 25 of Teva's Counterclaims and refers to the Ellis Affidavit with respect to its contents.

26. Pfizer denies the allegations contained in paragraph 26 of Teva's Counterclaims, except admits that the '012 patent issued on October 22, 2002, and refers to the claims of the '012 patent with respect to their contents.

27. Pfizer denies the allegations contained in paragraph 27 of Teva's Counterclaims and refers to claims 20, 25 and 26 of the '012 patent with respect to their contents.

28. Pfizer denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding Teva's beliefs set forth in paragraph 28 of Teva's Counterclaims. Pfizer denies any allegations of wrongdoing on the part of Dr. Ellis and Messrs. Benson, Jones, and O'Rourke.

29. Pfizer denies the allegations contained in paragraph 29 of Teva's Counterclaims, except admits that on September 10, 2002, Pfizer filed a Statement of Defense in Canadian Federal Court and refers thereto, to the Canadian Disclaimer, and to Bayer's December 5, 2002 Reply with respect to their contents.

30. In response to paragraph 30 of Teva's Counterclaims, Pfizer admits, upon information and belief, that attorneys at Bereskin & Parr spoke with Peter Ellis prior to the filing of the Canadian Disclaimer with the CIPO.

31. Pfizer denies the allegations contained in paragraph 31 of Teva's Counterclaims, except admits that in at least 2001 and 2002, Pfizer Inc.'s U.S. patent counsel received documents from patent proceedings and lawsuits relating to foreign counterparts of the '012 patent from Pfizer Limited's patent department; that on March 1, 2002, Lilly ICOS LLC and Eli Lilly Canada Inc. (collectively, "Lilly") filed a lawsuit against Pfizer R&D in Canadian Federal Court alleging that the Canadian '446 patent was invalid; and that on June 12, 2002, Counsel at Smart & Biggar forwarded a copy of Bayer's allegations in Canadian Case No. T-865-02 to Mr. McMunn. Pfizer denies knowledge or information sufficient to form a current belief as to the truth of the allegations contained in the fourth, fifth, and last sentences of paragraph 31 of the Teva Counterclaims.

32. Pfizer denies the allegations contained in paragraph 32 of Teva's Counterclaims, except admits that in 2001 Pfizer filed several Information Disclosure Statements with the PTO in connection with the prosecution of the '012 patent and refers thereto with respect to their contents.

33. Pfizer denies the allegations contained in paragraph 33 of Teva's Counterclaims and refers to the '012 patent file history and to the Canadian Disclaimer with respect to their contents.

34. Pfizer denies the allegations contained in paragraph 34 of Teva's Counterclaims and refers to the '012 patent file history with respect to its contents.

35. Pfizer denies the allegations contained in paragraph 35 of Teva's Counterclaims, except admits that on February 10, 1998, Pfizer filed a Response to Final Office Action with the PTO and refers thereto with respect to its contents.

36. Pfizer denies the allegations contained in paragraph 36 of Teva's Counterclaims, except admits that Pfizer submitted with its February 10, 1998 Response a First Declaration under 37 C.F.R. § 1.132 signed by Pfizer researcher Stephen A. Ballard and refers thereto with respect to its contents.

37. Pfizer denies the allegations contained in paragraph 37 of Teva's Counterclaims, except admits that on August 4, 1998, Pfizer filed a Brief of Appellants under 37 C.F.R. § 1.192 and refers thereto with respect to its contents.

38. Pfizer denies the allegations contained in paragraph 38 of Teva's Counterclaims, except admits that the '012 patent issued on October 22, 2002 and refers thereto with respect to its contents.

39. Pfizer denies the allegations contained in paragraph 39 of Teva's Counterclaims, except admits that on February 27, 1996, Dr. Ellis executed a Combined Declaration for Patent Application and Power of Attorney in connection with the application for the '012 patent which was submitted to the PTO on March 4, 1996, and refers thereto with respect to its contents. To the extent that paragraph 39 of Teva's Counterclaims sets forth legal conclusions, no response is required.

40. Pfizer denies the allegations contained in paragraph 40 of Teva's Counterclaims and refers to the '012 patent file history with respect to its contents.

41. Pfizer denies the allegations contained in paragraph 41 of Teva's Counterclaims. To the extent that paragraph 41 of Teva's Counterclaims sets forth legal conclusions, no response is required.

42. Pfizer denies the allegations contained in paragraph 42 of Teva's Counterclaims.

43. Pfizer denies the allegations contained in paragraph 43 of Teva's Counterclaims.

44. Pfizer denies the allegations contained in paragraph 44 of Teva's Counterclaims.

45. Pfizer denies the allegations contained in paragraph 45 of Teva's Counterclaims.

46. Pfizer denies the allegations contained in paragraph 46 of Teva's Counterclaims.

47. Pfizer denies the allegations contained in paragraph 47 of Teva's Counterclaims.

48. Pfizer denies the allegations contained in paragraph 48 of Teva's Counterclaims and refers to the '012 patent reexamination file history with respect to its contents.

49. Paragraph 49 of Teva's Counterclaims sets forth a legal conclusion to which no response is required.

50. Pfizer denies the allegations contained in paragraph 50 of Teva's Counterclaims, except admits that Pfizer submitted to the PTO declarations signed by Dr. Ellis on March 29, 2005, and November 11, 2005, and refers thereto and to the Ellis Affidavit in Canada with respect to their contents.

51. Pfizer denies the allegations contained in paragraph 51 of Teva's Counterclaims and refers to the '012 reexamination patent file history with respect to its contents. To the extent paragraph 51 of Teva's Counterclaims sets forth legal conclusions, no response is required.

52. Pfizer denies the allegations contained in paragraph 52 of Teva's Counterclaims.

53. Pfizer denies the allegations contained in paragraph 53 of Teva's Counterclaims and refers to the '012 patent reexamination file history with respect to its contents.

54. Pfizer denies the allegations contained in paragraph 54 of Teva's Counterclaims and refers to the '012 patent reexamination file history with respect to its contents.

55. Pfizer denies the allegations contained in paragraph 55 of Teva's Counterclaims, except admits that in Canadian Case No. T-1314-05, Pfizer sued to prevent Apotex from obtaining regulatory approval to market a generic version of Viagra® in Canada until after the expiration of the Canadian '446 patent and refers to Apotex's May 11, 2007 Memorandum of Fact and Law submitted in connection with the Canadian Case No. T-1314-05 with respect to its contents.

56. Pfizer denies the allegations contained in paragraph 56 of Teva's Counterclaims, except admits that Apotex appealed the ruling in Canadian Case No. T-1314-05 in Canadian Case No. A-484-07 and refers to Apotex's April 8, 2008 Memorandum of Fact and Law submitted in connection Canadian Case No. A-484-07 with respect to its contents.

57. Pfizer denies the allegations contained in paragraph 57 of Teva's Counterclaims. and refers to the '012 patent reexamination file history with respect to its contents.

58. Pfizer denies the allegations contained in paragraph 58 of Teva's Counterclaims and refers to the '012 patent reexamination file history with respect to its contents.

59. Pfizer denies the allegations contained in paragraph 59 of Teva's Counterclaims.

60. Pfizer denies the allegations contained in paragraph 60 of Teva's Counterclaims.

61. Pfizer denies the allegations contained in paragraph 61 of Teva's Counterclaims.

#### **Pfizer's Affirmative Defense**

62. Teva's Counterclaims fail to state claims upon which relief can be granted.

#### **PRAYER FOR RELIEF**

WHEREFORE, Pfizer requests that the Court enter judgment in its favor and against Teva as follows:



- A. Dismissing the Counterclaims with prejudice.
- B. Declaring that Teva's submission of ANDA No. 77-342 was an act of infringement and that Teva's making, using, offering to sell, selling or importing the ANDA Products prior to the expiration of the '012 patent will infringe, actively induce infringement and/or contribute to the infringement of the '012 patent.
- C. Declaring that claims 25 and 26 of the '012 patent are valid and enforceable; and
- D. Such further and additional relief as this Court deems just and proper.

Dated: February 2, 2011

/s/

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**CERTIFICATE OF SERVICE**

I hereby certify that, on February 2, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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